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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/726,962

12/03/2003

David Ernest Hartley

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9896 7590 11/02/2007  
COOK GROUP PATENT OFFICE  
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EXAMINER

DOWE, KATHERINE MARIE

ART UNIT

PAPER NUMBER

3734

MAIL DATE

DELIVERY MODE

11/02/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/726,962	Applicant(s) HARTLEY ET AL.	
	Examiner Katherine M. Dowe	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 August 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 19,21-23 and 25-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 19,21-23 and 25-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. The following is a complete response to the amendment filed 8/16/2007.
2. Claims 19, 21-23, and 25-27 are currently pending.

### ***Claim Rejections - 35 USC § 103***

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 19, 23, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chobotov et al. (US 2002/0151953) in view of Ivancev et al. (US 6,773,457). Regarding claims 19 and 25, Chobotov et al. disclose the invention substantially as claimed including a prosthesis (11) mounted on a deployment device (Fig 1) comprising a deployment catheter (53) coaxially around a central catheter (207) with a distal end designed to be inserted in the descending aorta (para 0074). The distal end of the central catheter comprises a nose cone (44), which uses a trigger wire (24) to retain the distal end of the prosthesis (para 0085). However, Chobotov et al. do not disclose the prosthesis is everted during deployment. Ivancev et al. disclose a similar method for inserting a prosthesis (Fig 1) in the aorta (col 2, ln 24-29). Ivancev et al. teach a deployment method to insert the prosthesis in the ascending and descending aorta in which the ascending portion of the graft is inverted down into the descending portion of the graft initially. The inverted device is inserted into the descending aorta (Fig 4), fixed in place, then the ascending portion of the graft is inverted and placed in the ascending aorta (Fig 5). Thus, the surgeon is able to conduct the surgery more

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quickly such that the patient will be able to reestablish circulation faster (col 2, ln 29-33; col 6, ln 31-51). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Chobotov et al. such that the prosthesis was everted and a folded central portion extended to the proximal end of the deployment device and the prosthesis proximal and distal ends extended to a distal end of the deployment device to simplify the deployment method of deploying the prosthesis in the ascending and descending aorta, thereby reducing the surgical time and thus the risk for the patient. Furthermore, since Chobotov et al. teach attaching the ends of the prosthesis to the proximal and distal ends of the deployment catheter, wherein the deployment catheter is attached to the nose cone at the distal end, it would have been obvious to mount the everted prosthesis in the same way. Finally, the manipulator that the central portion is mounted to on the proximal end, may be interpreted as the release wire 23.

Regarding claim 23, Chobotov et al. additionally do not disclose the prosthesis is formed from a corrugated material. Ivancev et al. disclose a similar prosthesis (1) that may be deployed in the aorta (col 4, ln 60-67). Ivancev et al. teach the prosthesis should be corrugated to promote setting of the graft in a curved shape and promote the flexibility of the graft (col 5, ln 10-12). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Chobotov et al. such that the prosthesis was formed from a corrugated material such that it may be more flexible and easier to place in the aorta.

5. Claims 21, 22, 26, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chobotov et al. (US 2002/0151953) and Ivancev et al. (US 6,773,457), as applied to claims 19 and 25 above, in view of Cook et al. (US 7,175,652). Chobotov et al. and Ivancev et al. disclose the invention substantially as claimed as shown above. Chobotov et al. disclose the prosthesis comprises an uncovered self-expanding stent (33) extending from the distal end of the prosthesis. Additionally, the prosthesis itself is structurally supported by inflatable cuffs (30 and 28) and inflatable channels (284). However, Chobotov et al. do not disclose the prosthesis comprises an internal self-expanding stent or that the uncovered stent comprises barbs. Cook et al. disclose a similar prosthesis that may be placed in the aorta. Cook et al. teach the prosthesis may be supported by an internal self-expanding stent (40) with barbs (36) and an extending uncovered self-expanding stent (18). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Chobotov et al. such that the uncovered stent comprised barbs and such that the prosthesis comprised an internal self-expanding stent in place of the inflatable cuffs and channels. Thus the prosthesis would have a more stable structure and could be better anchored and secured upon delivery. Additionally, regarding claims 26 and 27, it is obvious that if the prosthesis comprised an internal stent and barbs as shown above, the trigger wire, which retains the entire prosthesis in Chobotov et al., would also retain the internal stent and barbs since it is inherent that if the outer prosthesis and outer uncovered stent are in a contracted condition, the internal stent and internal barbs must also be in a contracted condition.

***Response to Arguments***

6. Applicant's arguments filed 8/16/2007 have been fully considered but they are not persuasive. Applicant argues Ivancev et al. teaches an entirely manual method of introducing a prosthesis and thus there is no teaching or suggestion how the central portion and proximal/distal ends of the prosthesis are maintained on a delivery system. The Examiner respectfully traverses the applicant's remarks. The teaching of Ivancev et al. is used to show the method of everting a prosthesis to more efficiently deliver the prosthesis to the aorta. Thus, the teaching of Ivancev is used to modify the base reference of Chobotov et al. who teaches mounting a prosthesis at proximal and distal ends of a deployment device. When the prosthesis of Chobotov et al. is everted in view of Ivancev et al., the proximal end of the prosthesis becomes the central folded portion of the prosthesis and the distal end of the prosthesis becomes both the proximal and distal ends of the prosthesis. Thus, when mounted in the same manner as the original prosthesis in Chobotov et al., the modified prosthesis has the central portion mounted to the delivery catheter proximal end and the proximal and distal prosthesis ends mounted to the delivery catheter distal end. Furthermore, when the prosthesis ends are mounted to the delivery catheter distal end, they may also be interpreted as mounted to the nose cone dilator, since the nose cone dilator is fixed to the delivery catheter distal end.

***Conclusion***

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Katherine M. Dowe whose telephone number is (571) 272-3201. The examiner can normally be reached on M-F 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Katherine Dowe   
October 26, 2007



MICHAEL J. HAYES  
SUPERVISORY PATENT EXAMINER